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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/852,020	05/06/1997	ICHIRO MARUYAMA		6556

7590

05/03/2004

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2/14  
**Advisory Action**

Application No.

08/852,020

Applicant(s)

MARUYAMA ET AL.

Examiner

Gerald G Leffers Jr., PhD

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 19 April 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 57-60.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit: 1636

*Advisory Action Attachment*

**Continuation of 2. NOTE:** The proposed amendment, while obviating rejections made under 35 U.S.C. 112 1st paragraph, would raise a new issue of Statutory Double Patenting for instant claim 57 over claim 1 of U.S. Patent 5,627,024. In short, both claims are drawn to a recombinant lambdoid bacteriophage vector comprising a nucleotide sequence that defines the lambdoid elements for replication and packaging of the vector into an assembled bacteriophage, and encodes a conditionally suppressible cistron for expression of a matrix anchor protein and a fusion protein where the matrix anchor protein is pV. In the patent claim the pV polypeptide is referred to as a tail protein, which is also accurate but does not differentiate over the same polypeptide when it is referred to as a matrix anchor protein.

In an attempt to ascertain any differences between claim 1 of the '024 patent and instant claim 57, the examiner called applicants' representative, Mr. Michael McCarthy, to discuss the scope encompassed by claim 1 of the '024 patent and how it may differ in scope from instant claim 57 (see the attached Interview Summary). The examiner contends the scope is the same and Statutory Double Patenting would be an issue. Mr. McCarthy contends that instant claim 57 encompasses an embodiment where matrix anchor proteins other than pV are expressed as part of the same cistron that encodes pV and the pV/fusion protein. No agreement was reached and Mr. McCarthy was notified that an Advisory Action would be forthcoming.

Each of the claims is directed to "a conditionally suppressible cistron for expression of a matrix anchor protein and a fusion protein" where the cistron comprises 1) a promoter for transcribing the cistron, 2) a first upstream translatable sequence that encodes a pV lambdoid bacteriophage polypeptide (whether referred to as a matrix anchor protein or tail protein), 3) a

Art Unit: 1636

first ribosome binding site to initiate translation of the upstream translatable sequence, 4) a second translatable sequence operatively linked downstream to the first translatable sequence (i.e. pV) where the second translatable sequence encodes a linker polypeptide and where it comprises an insertion sequence for insertion of a third translatable sequence (encoding a preselected polypeptide) downstream from the second translatable sequence, and 5) a suppressible termination codon within the second translatable sequence that upon suppression results in read-through to form a fusion polypeptide consisting of the pV polypeptide, linker polypeptide and the preselected polypeptide. Given the claim structure, and that the term “cistron” is normally construed as comprising a single coding sequence encoding a structural protein (see the definition provided below), it is not reasonable to construe instant claim 57 as encompassing addition sequences encoding additional anchor matrix proteins in addition to pV. While it is conceded that the cistron recited in claim 57 actually encodes two different proteins due to the suppressible termination codon present in the second translatable sequence, each of these proteins necessarily comprises pV as the claim is currently written and no other matrix anchor protein. Support for other embodiments where, for example, the pV fusion protein comprises sequences encoding other anchor matrix anchor proteins does not appear to be present in the instant specification. Therefore, the proposed amendment of claim 57 would necessarily raise additional issues regarding Statutory Double Patenting and will not be entered.

**Stedman's Online Medical Dictionary:**

**cistron (sis' tron)**

- 1. The smallest functional unit of heritability; a length of chromosomal DNA associated with a single biochemical function. Under classical concepts, a gene might consist of more than one cistron; in modern molecular biology, the cistron is essentially equivalent to the structural gene.**
- 2. The genetic unit defined by the *cis/trans* test.**

Art Unit: 1636

**Continuation of 5. does NOT place the application in condition for allowance because:**


arguments directed to the proposed amendment are moot as the amendment has not been entered into the file.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GERRY LEFFERS  
PRIMARY EXAMINER  
Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl